K032546

OCT 16 2003

H. 510(k) Summary

H.1 Company Identification

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730
781-999-7300

H.2 Contact Information

Daniel F. Phelan
Senior Regulatory Affairs Specialist

H.3 Date of Submission

August 13, 2003

H.4 Device Identification

Proprietary Name	Hologic DR ImagePro
Classification Name:	Picture Archiving and Communications System
Regulation Number:	21 CFR 820.2050
Product Code:	90 LLZ
Common/Usual Name	Medical Image Management Device

H.5 Predicate Device Information

K990241 AccuImage Diagnostics Corp. AccuView Diagnostic Imaging Software Package with Plug-ins.

H.6 Device Description and Intended Use

The Hologic DR ImagePro is a Windows-based software application acting as a Picture Archiving and Communications System (PACS). It is intended to be used by clinical professionals to view, manipulate, transmit, print, and store DICOM compliant digital radiographic image data. It provides standard tools for image zoom, rotation, enhancement, smoothing, and sharpening. Hologic DR ImagePro also provides software tools for merging two to five DICOM image files of an individual patient together to aid visualization of large areas of interest. The software assists users in merging, or "stitching," the separate images together manually and allows users to draw lines and angles within the images to obtain measurements. The software runs on standard, off-the-shelf PC components.

H.7 Software

Hologic, Inc. certifies that the DR ImagePro software package is designed, developed, verified, and validated in accordance with written procedures as required by 21 CFR 820 and Hologic's quality system.

H.8 Hazard/Risk Analysis

The DR ImagePro does not contact the patient and is not intended to sustain life or control life-sustaining devices. Risk analysis has been performed throughout the development process in accordance with design control procedures. Particular attention has been paid to identifying potential hazards, assessing any potential effect on the safety of patients and the effectiveness of the device, determining the causes and effects of potential hazards, implementing mitigation measures, and to maintaining records of risk analysis and mitigation measures.

The potential risks identified through risk analysis activities are no different that those of other PACS devices. None of the risks is expected to cause or contribute to patient death or serious injury. Hologic therefore concludes that the Level of Concern posed by DR ImagePro is "minor."

H.9 Substantial Equivalence

Manufacturer	Hologic, Inc.	AccuImage Diagnostics Corp
510(k) Number	[redacted]	K990241
Proprietary Name	**DR ImagePro**	**Accuview Diagnostic Imaging Software Package with Plug-ins.**
Computer Platform	Standard PC, Windows XP OS, ≥ 2.0GHz processor, ≥ 512 MB RAM.	Standard PC, Windows 95/98/NT OS, 400MHz processor, 512 MB RAM
Communications	TCP/IP Ethernet	TCP/IP Ethernet, GPIB
Image Format (input)	DICOM 3.0	DICOM 3.0, ACR NEMA 2.0
Image Format (output)	DICOM 3.0	DICOM 3.0, BMP, TIFF
Storage Media	PACS/Ethernet Network, Local Disk.	PACS/Ethernet Network, Local Disk, CD-ROM
Display / Monitor Requirements	≥ 18" Color, CRT or LCD, SXGA 1280 X 1024	Color/Grayscale, CRT or Laptop LCD, Up to 1024 X 768
Image Processing	Window/Level, Pan, Zoom, Grayscale Invert, Contrast Enhance, Sharpen, Blur, Rotate, Crop, Side-by-side Display.	Window/Level, Pan, Zoom, Variable Smooth Filter, Cine Display
Image Stitching	Merge images from the same patient/study. Manual selection of common stitch points within images. Software stitches user-placed common points.	Merge images from the same patient/study (patient/study data obtained from DICOM header). Manual selection of common stitch points within images. Software stitches user-placed common points or lines.
Line Measurement Tool	Measures distances from user-placed points on image Measurements derived from pixel size specified in DICOM header.	Measures distances from user-placed points on image Measurements derived from pixel size specified in DICOM header..
Angle Measurement Tool	Measures angles from user-placed points on image.	Measures angles from user-placed points on image.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2003

Mr. Daniel F. Phelan
Senior Regulatory Affairs Specialist
HOLOGIC, Inc.
35 Crosby Drive
BEDFORD MA 01730

Re: K032546
Trade/Device Name: Hologic DR ImagePro Software Package
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 15, 2003
Received: August 18, 2003

Dear Mr. Phelan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K032546

B.2 Indications for Use

The Hologic DR ImagePro is a Windows-based software application acting as a Picture Archiving and Communications System (PACS). It is intended to be used by clinical professionals to view, manipulate, transmit, print, and store DICOM compliant digital radiographic image data. It provides standard tools for image zoom, rotation, enhancement, smoothing, and sharpening. Hologic DR ImagePro also provides software tools for merging two to five DICOM image files of an individual patient together to aid visualization of large areas of interest. The software assists users in merging, or "stitching," the separate images together manually and allows users to draw lines and angles within the images to obtain measurements. The software runs on standard, off-the-shelf PC components.

Prescription Use ✓

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032546